

**toXcel****Toxicology & Regulatory Affairs**7140 Heritage Village Plaza  
Gainesville, VA 20155-3061

Phone: (703) 754-0248

Fax: (703) 310-6950

**HAND DELIVERED**

April 1, 2015

Mr. Demson Fuller (PM-32)  
Antimicrobial Division  
Document Processing Desk (PROPOSAL)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501

RE: Draft Efficacy Study Proposal for *Sodium Chlorite Technical*,  
EPA File Symbol 90094-1

Dear Mr. Fuller:

On behalf of DRS Laboratories, Inc., we are submitting the enclosed draft efficacy study protocol for "Sodium Chlorite Technical", which contains the active ingredient Sodium chlorite at 80%.

The purpose of the enclosed efficacy study protocol is to get EPA's acceptance of this approach to develop efficacy data that will support the use of this product to generate gaseous Chlorine dioxide for use in the registrant's Mini-CD System<sup>®</sup> to decontaminate biological safety cabinets. This draft protocol submission is for EPA review under PRIA Category A521 (3 month review; \$591 fee with the small business waiver). This submission is necessitated by the Agency's rejection of the NSF/ANSI Standard 49 efficacy study submitted with the February 18, 2014 label amendment. That label amendment was voluntarily withdrawn on October 15, 2014 at the strong recommendation of the Agency and with the Agency's assurance that timely guidance as to the design of an acceptable replacement study protocol would be provided. In the absence of the Agency's provision of key details required for protocol development, the enclosed proposed efficacy study protocol is submitted for review under PRIA Category A521.

As required, the following documentation has been provided:

1. Amendment Application (EPA Form 8570-1)
2. Reference to prior Small Business Fee Waiver, Decision No. D-488000

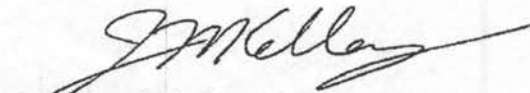
Mr. Demson Fuller  
April 1, 2015  
Page 2 of 2

3. PRIA Payment Confirmation
4. Labeling (Master label and Mini-CD System® Instruction Manual – one paper copy each)
5. Draft Efficacy Study Protocol for EPA Review and Input

It is our understanding that this label amendment application will be processed under PRIA category A521 in a timeframe of three (3) months.

If you have any questions or require additional information, please contact me by email at [mike.kelley@toxcel.com](mailto:mike.kelley@toxcel.com) or by phone at 703-754-0248 x112.

Sincerely,



J. Michael Kelley, Ph.D.  
Authorized Representative for DRS Laboratories, Inc.  
Vice President, toXcel, LLC

Enclosures

CC: Mike Regits (DRS Labs)

## TRANSMITTAL DOCUMENT

1. **Name and Address of Submitter**

DRS Laboratories, Inc.  
PO Box 20247  
Lehigh Valley, PA 18002

Authorized Representative  
toXcel, LLC  
7140 Heritage Village Plaza  
Gainesville, VA 20155

2. **Regulatory Action**

Submission of Draft Efficacy Study Proposal for *Sodium Chlorite Technical*,  
EPA File Symbol 90094-1

3. **Transmittal Date**

1 April 2015

4. **List of Submitted Studies/Documents**

MRID \_\_\_\_\_ **Admin**

Cover Letter  
Transmittal Document  
EPA Form 8570-1  
Reference to prior Small Business Waiver  
PRIA Payment Confirmation  
Master Label  
Mini-CD System® Instruction Manual

MRID 49605601 **Volume 1**

Proposed Protocol to Support Use of EPA Reg. No.  
90094-1 with the Mini Chlorine Dioxide System (MCS) to  
Sterilize/Decontaminate Confined Areas, Specifically  
Including Biological Safety Cabinets

**Company Name/Representative:**

Company Name: DRS Laboratories, Inc.

Authorized Representative:

  
J. Michael Kelley, PhD  
toXcel LLC  
7140 Heritage Village Plaza  
Gainesville, VA 20155  
Email: Mike.Kelley@toxcel.com  
Telephone: (703) 754-0248 x112  
Fax: (703) 310-6950

1 April 2015  
Date